K090460

5. 510(k) summary

Preparation date: February 13, 2009

Submitter:

aap Biomaterials GmbH
Lagerstraße 11-15
64807 Dieburg
Germany
Phone: +49 6071 / 929-0
Fax: +49 6071 / 929-100

APR 14 2009

Contact person: Volker Stirnal

Trade name: BonOs® Inject

Common name: PMMA Bone Cement (For Vertebroplasty)

Classification: Polymethylmethacrylate (PMMA) Bone Cement
21 CFR 888.3027, Class II

Product Code: LOD, NDN

Panel: Orthopedics

Predicate device to which substantial equivalence is claimed:

Manufaturer	Device Name	510(k) #
Heraeus Kulzer GmbH	OSTEOPAL® V	(K050085)

Device description:

BonOs® Inject is a radiopaque, injectable bone cement for use in spine surgery like percutaneous vertebral augmentation during vertebroplasty or kyphoplasty. It is a two-component system consisting of a powder and a liquid. Methylmethacrylate polymer is the primary constituent of the powder component. Zirconium dioxide is added as radiopacifier. Methylmethacrylate monomer is the primary constituent of the liquid component. Mixing the two separate sterile components, initially an injectable paste is produced which can be transferred into a syringe and which then can be injected under slight pressure into the vertebral body. After curing of the bone cement by exothermic polymerization it stabilizes the vertebral lesions and vertebral compression fractures.

Scientific concepts, significant physical and performance characteristics:

Bone cements in general are self-polymerizing two-component systems comprising a powder and a liquid which polymerize at room temperature immediately after they are mixed together.

The bone cement powder mainly consists of polymethylmethacrylate (PMMA), benzoyl peroxide (BPO) as initiator and zirconium dioxide as radiopacifier.
The liquid component comprises monomer methylmethacrylate (MMA) and N,N-dimethyl-p-toluidine (DmpT) as activator. Additionally MMA is stabilized with hydroquinone (HQ).

When the two components are mixed together, the activator DmpT contained in the liquid activates the initiator BPO. This reaction starts polymerization of the monomer MMA, which cross-links with the polymer powder during the ongoing polymerization. As a result, a viscous injectable mass is obtained which can be introduced into the vertebral fracture using a suitable application system. Heat is generated during setting as a result of the progressive polymerization and exothermic reaction respectively. The setting or curing time is greatly influenced by the temperature of the components and environment.

Statement of the intended use:

BonOs® Inject bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

Summary of technological characteristics of the new device in comparison to the predicate device:

BonOs® Inject comprises the same chemical components as the legally marketed device OSTEOPAL®V. BonOs® Inject has been and is down to the present day successfully marketed in Europe.

The effectiveness and substantial equivalence of BonOs® Inject was determined by physical, chemical and mechanical comparative tests to OSTEOPAL®V and by comparing the results of the relevant data.

In summary, BonOs® Inject is safe and effective for the declared indications and substantially equivalent to OSTEOPAL®V.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

aap Biomaterials GmbH
% Mr. Volker Stirnal
Director QA/RA
Lagerstrasse 11-15
D 64807 Dieburg
Germany

APR 14 2009

Re: K090460
Trade/Device Name: BonOs® Inject
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: February 13, 2009
Received: February 23, 2009

Dear Mr. Stirnal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number:

Device Name: BonOs® Inject

Indications for Use:

BonOs® Inject bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090460